

## **LABELLING**

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

Carton label

### **1. Name of the medicinal product**

[TB236 trade name]\* Cycloserine 250 mg capsules  
Cycloserine

### **2. Statement of active substance**

Each hard gelatin capsule contains 250 mg cycloserine

### **3. List of excipients**

Contains FD&C Yellow #6 (sunset yellow FCF)

### **4. Pharmaceutical form and contents**

Hard gelatin capsule  
10 x 10 capsules

### **5. Method and route of administration**

Oral use  
Read the patient information leaflet before use.

### **6. Special warning that the medicinal product must be stored out of the reach and sight of children**

Keep this medicine out of the sight and reach of children.

### **7. Other special warning(s), if necessary**

### **8. Expiry date**

EXP {MM/YYYY}

### **9. Special storage conditions**

Store below 30°C in a dry place and protected from moisture.

### **10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**

### **11. Name and address of the supplier**

Dong-A ST Co Limited  
64, Cheonho-daero, Dongdaemun-gu  
Seoul  
Korea

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\* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

**12. WHO Reference Number (Prequalification Programme)**

TB236

**13. Manufacturer's batch number**

<Batch> <Lot> {number}

**14. (Advice on) General classification for supply**

Medicinal product subject to medical prescription.

**15. Instructions on use**

## **MINIMUM PARTICULARS TO APPEAR ON BLISTERS**

Alu-Alu blisters

### **1. Name of the medicinal product**

[TB236 trade name] Cycloserine 250 mg capsules

Cycloserine

### **2. Name of the supplier**

Dong-A ST Co Limited

### **3. Expiry date**

EXP {MM/YYYY}

### **4. Manufacturer's batch number**

<Batch> <Lot> {number}

### **5. Other**